

between the lines

Darrin Baines

The Italian job

As both NICE and the Leaning Tower bear witness to, all things must have solid foundations

Italy has many beautiful things to offer; even the best British film ever – *The Italian Job* – was based in the bloody place.

Amongst the beauty, the class, the good taste, there remains one mystery – why is the Leaning Tower of Pisa still standing?

With the Tower tipping over at the rate of one millimetre a year since the early 1900s, expert after expert has predicted its demise. In response, many pessimists felt that the only real course of action worth taking was to sit back, pop open a Chianti and let gravity take its course.

However, many Italian politicians, officials, academics and tourists have refused to be beaten by the power of nature, and have made many attempts to rectify the tower's tilt and there are good signs from the most recent attempts.

So, are the Italians in a blind alley? Although they know that the Tower hasn't fallen down yet, they don't know what the future holds.

An uncertain start

NICE was built on shaky foundations. The idea that NHS rationing policy can be built on evidence produced during clinical and cost-effectiveness studies was dubious from the start.

Before the introduction of NICE, the UK did not base health service decision-making on clinical or economic evidence; although evidence from Canada and Australia suggested that health technology dissemination could be controlled in this way.

In recent months, as I sit back of an evening and enjoy my daily bottle of Chianti, I contemplate the naivety of the policy-makers who introduced NICE and ask myself whether they actually knew how insecure the body's foundations actually are.

An increasing number of civil servants, academics, qualified experts and generally unqualified individuals are now running around the NHS trying to find ways of artificially propping up the Government's decision-making edifice.

I thought I would try and halt their wasted efforts by exposing NICE's three most fundamental flaws.

Firstly, as the Institute bases its decisions upon observational trials that generate clinical and economic data, it may be argued that the body's decisions fall foul of what philosophers call the 'naturalistic fallacy', that is, assuming that the word



'is' automatically implies 'ought'.

In other words, clinical and economic trials simply observe the degree to which evaluated health technologies work under extremely controlled conditions; they do not tell us anything about the policies the NHS should subsequently adopt.

For example, if NICE found that beta interferon produces relatively few health benefits (compared to other health technologies), this finding is not enough to recommend against its use.

Indeed, it could be argued that the 'rule of rescue' applies to this patient group, and that the most important factor is not

effectiveness or cost-effectiveness but simply trying to help those suffering.

Therefore, to avoid the naturalistic fallacy, policy-makers have to introduce an 'evaluative premise' that transforms what is observable into a set of rules that should be followed.

Clinical or economic trials are not enough and someone, somewhere has to make a policy decision that can be guided by trial data, but has to take into account many more factors than just effectiveness and economy.

However, whilst patients, clinicians, managers and politicians are equipped to ►►

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► make these decisions I would strongly argue that the folk at NICE and the experts on their 'hanging committees' have no right to make social decisions that affect our lives whilst pretending they are simply acting on evidence.

The second fallacy that threatens NICE's future is the 'ecological fallacy'.

This states that individual members of a population don't all have the same characteristics – to the same extent – of the groups to which they belong. For example, if you live in a deprived area with 20 per cent unemployment, you are either in employment or out-of-work, no one is actually 20 per cent unemployed.

As clinical trials and economic evaluations are based upon population data, they calculate 'average effects'. Consequently, if a trial shows that a new intervention produces – on average – a life gain of two months for the 'average' patient, this does not mean that all future users of the product will live eight weeks longer.

On the contrary, most patients are unlikely to benefit from such an intervention, whilst a handful may live much longer than the observed two months.

Therefore, clinical trial and economic evaluation data are almost useless to decision-makers, as doctors and nurses will always be able to find patients that beat their average results.

Therefore, NICE is effectively promoting

decision-making that may work at a population level that gives individuals no chance of beating the mean.

The big issue

But NICE's biggest problem of all is a belief in the fallacy that 'ought implies can' – which states that we cannot always do what we should be doing.

For example, I know I should be at the gym today getting fitter but I can't because the hangover caused by last night's bottle of Chianti has rendered me incapable. Therefore, ought implies can... but I can't.

Similarly, NICE's main problem is not the intricacies of evaluating interventions on clinical or efficiency grounds, but that the NHS usually can't afford what it would like to recommend.

NICE should be less bothered about evaluating clinical trial and economic evaluation data – which is collected under fairy-tale conditions where all patients get treated and no rationing occurs. Instead, it should start collecting information on what actually happens to priorities, outcomes and efficiency once interventions are in the cash-strapped NHS.

Only by analysing information of this type, produced in real situations by real decision-makers, can NICE make sensible pronouncements on the priorities the health service should follow.

Why does NICE even bother evaluating pharmaceutical technologies, as their prices – across the board – are set by the PPRS agreement between the government and pharma? Under the PPRS, companies can launch new products at whatever prices they wish but their overall profits are capped by the amount of R&D investment they undertake in the UK.

What ultimately determines drug prices in this country is not clinical or economic effectiveness, but the amount pharma is willing to invest in the next generation of medicines for the NHS.

So when NICE doesn't recommend a drug because of its high price, it is simply affecting the producer's ability to undertake further R&D, denying both present and future patients the care they need.

Eventually the government will have to choose between the PPRS and NICE, as the former has the ability to undermine the whole foundation of the latter.

However, how long NICE survives will not depend upon the wishes of policy-makers, health economists or pharma company MDs but upon the clinicians, managers and others within the health service who are now responsible for making its decisions work in the NHS.

THE AUTHOR

Dr Darrin Baines is the director of medM. He can be contacted at director@medm.co.uk

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